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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY/DOCKET NO.
08/877,155	06/17/97	CORMIER	

QM31/0216

EXAMINER

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Please find below and/or attached an Office communication concerning this application or proceeding.

**Commissioner of Patents and Trademarks**

## Office Action Summary

Application No. <b>08/877,155</b>	Applicant(s) <b>Cormier et al</b>
Examiner <b>Sharon Finkel</b>	Group Art Unit <b>3763</b>



Responsive to communication(s) filed on Dec 23, 1998.

This action is **FINAL**.

Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 3 month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

### Disposition of Claims

Claim(s) 6, 7, 30, 31, and 53-91 is/are pending in the application.

Of the above, claim(s) \_\_\_\_\_ is/are withdrawn from consideration.

Claim(s) \_\_\_\_\_ is/are allowed.

Claim(s) 6, 7, 30, 31, 55-57, 59-74, 76, 78, and 80-91 is/are rejected.

Claim(s) 53, 54, 58, 75, 77, and 79 is/are objected to.

Claims \_\_\_\_\_ are subject to restriction or election requirement.

### Application Papers

See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

The drawing(s) filed on \_\_\_\_\_ is/are objected to by the Examiner.

The proposed drawing correction, filed on \_\_\_\_\_ is  approved  disapproved.

The specification is objected to by the Examiner.

The oath or declaration is objected to by the Examiner.

### Priority under 35 U.S.C. § 119

Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

All  Some\*  None of the CERTIFIED copies of the priority documents have been

received.

received in Application No. (Series Code/Serial Number) \_\_\_\_\_.

received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

\*Certified copies not received: \_\_\_\_\_

Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

### Attachment(s)

Notice of References Cited, PTO-892

Information Disclosure Statement(s), PTO-1449, Paper No(s). \_\_\_\_\_

Interview Summary, PTO-413

Notice of Draftsperson's Patent Drawing Review, PTO-948

Notice of Informal Patent Application, PTO-152

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

## DETAILED ACTION

### *Claim Rejections - 35 USC § 102*

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

2. Claims 6, 7, 30, 31, 55, 57, 59-62, 65, 66, 67, 68, 71-74, 76, 78, 80, 83-86, 89-91 are rejected under 35 U.S.C. 102(b) as being anticipated by Ganderton et al., 3,814,097. These claims are directed to generic claims or claims that include the limitation that the anchor may be a projection on a blade or the orientation of the blade. MPEP 2114 states that claims directed to an apparatus must be distinguished from the prior art in terms of structure rather than function. Ganderton discloses a metal sheet punctured with holes. See especially in column 2, lines 8-12. This puncturing inherently results in a conically extending through hole surrounded by an uneven row of triangular shaped projections, each with a different angle orientation. Accordingly, the resulting randomly oriented blades, which must be an inherent product of the puncturing, are seen to anticipate the claimed structure in view of the broad definition of the term "anchor." Applicant states that Ganderton fails to disclose an anchor, but an anchor is one of those structures which are defined primarily by their function. Since the claimed structures are identical, terming the structure as an anchor is not seen to define over the prior art. (Again, see MPEP 2114.) Distinguishing claims 56 and 75, here the anchor is further defined as preventing the sheet from being dislodged from the body surface. It is improbable that the Ganderton device with its

punched metal sheet can perform this function. Accordingly, this claim language makes it clear that the anchor must be something more than a mere sheet with holes punched therethrough. Regarding claims 73 and 91, clearly the metal will stress, thin and finally break as the puncturing occurs. Accordingly, it is inherent that the blades are thinner than the sheet. Regarding claim 76 and other claims containing similar claim language, again, the randomly oriented nature of the blades which result from the puncturing meet this limitation. As defined in the specification, the anchor may be differing angle orientations. Regarding claim 80, the broad definition of the openings in this claim does not preclude the reasonable interpretation that the openings of claim 80 and those defined in claim 30 are the same in structure.

3. Claims 6, 55-57, 59, 64-66, 71, 72 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by Reed et al., U.S. 5,312,456. See Figure 13. Although applicant states in the preamble that the intended use of the device is to deliver or withdraw substances through the stratum corneum, this use is non-limiting. See MPEP 2114, for example, for clarification. Regarding claim 57, the anchor is interpreted to be the Reed barb which is unlabeled in Figure 13. The barb is labeled as 16 in Figure 2. Clearly, the barb extends from the plane of the blade in Figure 13. (Applicant could perhaps clarify the language “extends out from” to more carefully characterize applicant’s Figure 10 and the similar figures, wherein the anchor and the blade are not in the same plane. This is not seen in the prior art of record.) Regarding the term “blade,” although there is an implication that this means that the edges are sharpened as in a knife, this specific limitation has not been claimed, and further a sharpening is not necessary for penetration. In other words, the term “blade” is being given as broad an interpretation as possible which is

consistent with applicant's specification. "Blade" merely means capable of penetrating the skin with a lesser degree of force than in a blunt surface, such as the blunt surface 24 in Figure 2 of the Reed patent. Accordingly, it is the Examiner's position that the pointed end of the barb 72 in Figure 13 of the Reed patent constitutes a "blade."

***Claim Rejections - 35 USC § 103***

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

5. Claims 63, 64, 69, 70, 81, 82, 87 and 88 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ganderton et al., U.S. 3,814,097. Regarding claims 63, 64, 81 and 82, Ganderton discloses the claimed subject matter as discussed above except Ganderton discloses 100 *or more* fibers per square centimeter. It is reasonable to interpret that in the case of projections, there may be 100 or more projections as well. Obviously, there is a great difference between the range claimed of 600 to 1000, preferably 800, and the 100 or more disclosed by Ganderton. With regard to claims 69, 70, 87 and 88, it is unclear what the size of the projection might be. Regardless, it appears apparent that this greater number of piercing elements and small size will result in an improved drug delivery device. Accordingly, it is seen as obvious to one of ordinary skill in the art to vary the size and number of the projections depending on the patient

need and the concentration of drug delivered. See also MPEP 2144.04, IV., A., which supports the Examiner's *prima facie* obviousness rejection.

6. Claims 7, 63, 69 and 70 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. 5,312,456. Reed fails to disclose the number of blades per square centimeter and the size of the blades. Regardless, it appears apparent that increasing numbers and decreasing sizes of blades, or visa versa, will result in an alternate drug delivery device which will deliver drugs at different rates. Accordingly, it is seen as obvious to one of ordinary skill in the art to vary the size and number of the projections depending on the patient need and the concentration of drug delivered. See also MPEP 2144.04, IV., A., which supports the Examiner's *prima facie* obviousness rejection. Regarding claim 7, it is obvious to one or ordinary skill in the art to deliver the type of drug necessary according to the patient's need.

#### *Allowable Subject Matter*

7. Claims 53, 54, 58, 75, 77, 79 would be allowable if rewritten to include all of the limitations of the base claim and any intervening claims.

8. The following is a statement of reasons for the indication of allowable subject matter: Regarding claims 53, 54, the prior art does not disclose or suggest an anchor in the form of adhesive on a surface of at least one of a plurality of blades. In addition, none of the prior art discloses or suggests an anchor which is a *prong* in combination with the agent delivery or sampling device. Applicant's arguments with the respect to the unobviousness of a combination the features of, for example, the Latterel '110 anchors and, for example, the embodiments of

Gerstel et al. '482 are noted and agreed with. Regarding claim 79, none of the prior art shows or remotely suggests this feature. Note that claim 30 and dependent claims therefrom have not been rejected in view of Reed et al., U.S. 5,312,456. Clearly, Reed does not disclose or suggest a plurality of blades located along a periphery of one opening. Regarding claim 75, here the anchor is further defined as preventing the sheet from being dislodged from the body surface. It is improbable that the Ganderton device or similar prior art of record can perform this function. Accordingly, this claim language makes it clear that the anchor must be something more than a mere sheet with holes punched therethrough or angled projections. Regarding claim 58 in view of Reed et al., US '272, clearly there is no motivation to alter the barbs 72 so that it has only one projecting extremity portion 26, particularly in view of the discussion concerning Figure 1 of the Reed et al. patent.

***Response to Arguments***

9. Applicant's arguments with respect to the claims have been considered but are moot in view of the new ground(s) of rejection. Again, as stated above, MPEP 2114 requires that claims directed to an apparatus must be distinguished from the prior art in terms of structure rather than function. Ganderton discloses a metal sheet punctured with holes. See especially in column 2, lines 8-12. This puncturing inherently results in a conically extending through hole surrounded by an uneven row of triangular shaped projections, each with a different angle orientation. Accordingly, the resulting randomly oriented blades, which must be an inherent product of the

puncturing, are seen to anticipate the claimed structure in view of the broad definition of the term "anchor" as defined in the specification.

*Conclusion*

10. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).
11. A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.
12. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sharon Finkel whose telephone number is (703) 305-0154.

  
Sharon Finkel

February 10, 1999

  
WINN WOOD COGGINS  
SUPERVISORY PATENT EXAMINER